

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : CROWE ET AL.  
Serial No. : 10/047,383  
For : **APPARATUS FOR STIMULATING A MUSCLE OF A  
SUBJECT**  
Filed : January 14, 2002  
Examiner : GEORGE EVANISKO  
Art Unit : 3762

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DECLARATION OF MICHAEL CONOR MINOGUE UNDER 37 C.F.R. §1.132

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, Michael Conor Minogue, declare and state that:

1. I make this statement in connection with U.S. Application Serial No. 10/047,383 ("the  
'383 application").

2. I am an Electronics Engineer and currently the Director for Research and Development at Bio-Medical Research, Ltd. of Galway Ireland., the assignee of the above-identified application, for which this declaration is being submitted.

3. I am a named inventor on PCT Application No. WO00/41764 (“the ‘764 application”), which I understand has been cited as a prior art reference against the ‘383 application.

4. The ‘764 describes a muscle stimulation system comprising an electrode belt which couples with an electronic pulse generator to stimulate the abdominal muscles. That specification details a wide range of electrical pulse parameters and electrode sizes which could be used in such a system for abdominal stimulation.

5. The system described in the ‘764 application could not be used to increase the subject’s calorie consumption to at least about three times its resting metabolic rate for at least the following reasons:

a. The abdominal muscles comprise only a small proportion of the body’s total muscle mass and even if the device described in the ‘764 application were used at maximum power they would not by themselves cause a subject’s calorie burn to be three times the resting metabolic rate. The number of calories burned can be determined by the demand for oxygen and these muscles on their own cannot create the required oxygen demand to create a three-fold increase in a subject’s calorie consumption. In order to create a significant demand for oxygen and a consequent increase in heart rate it is necessary to recruit much larger amounts of muscle fibres. Practically, this is for example achieved in the great muscles of the legs which together typically comprise nearly 50% of the body’s muscle mass.

b. The '764 application does not describe how to burn three times the calories a subject burns while resting. Although it refers to ranges of electrical pulse parameters, the '764 application does not identify which combination leads to thermogenic shivering, which is the mechanism by which the device of the '383 application burn calories. A stimulation pulse train is characterised by at least three parameters, pulse frequency, pulse width and pulse amplitude. The '383 application is precise in identifying a frequency range (3 to 12 Hz) combined with pulse width and pulse amplitude to as to produce very large charge-per-pulse (up to 200 $\mu$ C). The '764 application does not discuss a requirement or preference for electrical charge per pulse. Therefore a reading of this document alone, or in combination with others, would not teach the combination of electrical and timing parameters which leads to thermogenic shivering. The opposite is the more likely outcome in that a person of skill in the art is likely to choose a higher frequency in order to increase muscle fiber activity.

c. Using such a high stimulation charge-per-pulse creates a problem in that the pain receptors at the stimulation site are activated. The solution is to use a large electrode area so that the current density is reduced. The '764 application does not teach the combination of large electrode areas in combination with large charge per pulse such as to achieve low charge density. Without such a combination the stimulation would be very painful and the subject would be unable to tolerate the desired levels to achieve increasing the subject's calorie consumption to at least about three times its resting metabolic rate levels.

d. A stimulator which has the capacity to increase a subjects caloric consumption by a factor of three introduces a significant safety risk which may be unacceptable for many users. Such problems were not anticipated in the '764 application, as there was no need for such monitoring given the small muscle mass involved. In the '383 application, this problem is solved by the provision of a monitoring means preferably integrated as feedback into a control loop to regulate cardiovascular response.

6. Accordingly, the '764 application cannot be optimized or used to effect calorie consumption in a subject a three times the subjects resting metabolic rate.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:

October 10, 2005 - Michael Conor Minogue

Michael Conor Minogue